

- 1        1.        (Original) A water dispersible tablet formulation comprising an active ingredient as  
2                beta lactam antibiotic and optionally a beta lactamase inhibitor, a disintegrating agent,  
3                said disintegrating agent being used both intragranularly and extragranularly, and  
4                pharmaceutically accepted excipients.
- 1        2.        (Original) The formulation of claim 1 wherein said  $\beta$ -lactam antibiotic is selected  
2                from the group consisting of penicillin, cephalosporin and carbapenam.
- 1        3.        (Original) The formulation of claim 1 wherein said penicillin is amoxicillin, said  
2                cephalosporins is cefuroxime axetil, cefpodoxime proxetil or cefalexin and said  
3                carbapenam is loracarbef or imipenem.
- 1        4.        (Original) The formulation of claim 1 comprising the disintegrant selected from the  
2                group consisting of croscarmellose sodium, polyvinylpyrrolidone and sodium starch  
3                glycolate.
- 1        5.        (Currently Amended) The formulation of claim 1 ~~or 4~~ comprising about 1 % to about  
2                2.5 % w/w of an ~~the~~ intragranular disintegrant.
- 1        6.        (Currently Amended) The formulation of claim 1 ~~or 4~~ comprising about 1 % to about  
2                5 % w/w of an ~~the~~ extragranular disintegrant.
- 1        7.        (Currently Amended) The formulation of claim 1 comprising a ~~the~~ filler selected from  
2                the group consisting of lactose, microcrystalline cellulose and starch.
- 1        8.        (Currently Amended) The formulation of claim 1 further ~~or 7~~ comprising 40-70 %  
2                w/w of a ~~said~~ filler.
- 1        9.        (Original) The formulation of claim 1 comprising the lubricants selected from the  
2                group consisting of talc, magnesium stearate, stearic acid and colloidal silicon  
3                dioxide.

- 1        10.    (Original) The formulation of claim 1 wherein said dispersible tablet has a  
2                disintegration time of less than one minute.
- 1        11.    (Currently Amended) The formulation of claim 1 wherein said tablets form  
2                suspension after incorporating in aqueous media~~water~~.
- 1        12.    (Original) The formulation of claim 11 wherein said suspension formed completely  
2                passes through a 750  $\mu$ m sieve.
- 1        13.    (Original) The formulation of claim 1 wherein said beta lactamase inhibitor is  
2                clavulanic acid or a salt thereof.
- 1        14.    (Original) The formulation of claim 13 wherein the clavulanic acid salt is potassium  
2                clavulanate.
- 1        15.    (Currently Amended) The formulation of claim ~~13 or~~ 14 wherein the ratio of  
2                amoxicillin to potassium clavulanate is 12:1 to 1:1.
- 1        16.    (Original) The formulation of claim 15 wherein the ratio of amoxicillin to potassium  
2                clavulanate is 7:1.
- 1        17.    (Currently Amended) The formulation of claim ~~1 or~~ 11 wherein the tablet when  
2                dispersed in an aqueous media, has a particle size distribution of d90 less than 600  
3                 $\mu$ m.
- 1        18.    (Currently Amended) The formulation of claim ~~1 or~~ 11 wherein the tablet when  
2                dispersed in an aqueous media, has a particle size distribution of d90 less than 400  
3                 $\mu$ m.
- 1        19.    (Currently Amended) The formulation of claim ~~1 or~~ 11 wherein the tablet when  
2                dispersed in an aqueous media, has a particle size distribution of d50 less than 300  
3                 $\mu$ m.

- 1 20. (Currently Amended) A process for the preparation of a dispersible tablet comprising  
2 a beta lactam antibiotic, an optional beta lactamase inhibitor and an intragranular  
3 disintegrant, ~~said the process comprising: aqueous granulating of a beta lactam~~  
4 antibiotic, an optional beta lactamase inhibitor and an said intragranular disintegrant  
5 incorporated either in the dry mix or the granulating fluid, ~~are aqueous granulated,~~  
6 ~~dried, mixed; drying the granulation; missing the dried granulation with the~~  
7 extragranular disintegrant, a filler, a flavour, a lubricating agent, and a sweetener; and  
8 compressing the resulting blend ~~is compressed to into~~ tablets.
- 1 21. (Currently Amended) The process of claim 20 wherein the tablet  
2 ~~comprising~~comprises 30-50 % w/w amoxicillin.
- 1 22. (Currently Amended) The process of claim ~~20 or~~ 21 wherein the amoxicillin has a  
2 particle size of  $d_{90}$  less than 150  $\mu\text{m}$ .
- 1 23. (Currently Amended) The process of claim ~~20 or~~ 21 wherein the amoxicillin has a  
2 particle size of  $d_{90}$  less than 75  $\mu\text{m}$ .
- 1 24. (Currently Amended) The process of claim ~~20 or~~ 24 wherein the tablet comprising  
2 comprises about 1 % to about 2.5 % w/w of intragranular disintegrant.
- 1 25. (Currently Amended) The process of claim ~~20 or~~ 24 wherein the tablet comprising  
2 comprises about 1 % to about 5 % w/w of extragranular disintegrant.
- 1 26. (Original) The process of claim ~~24 or~~ 25 wherein the disintegrant is selected from the  
2 group consisting of croscarmellose sodium, polyvinylpyrrolidone and sodium starch  
3 glycolate.
- 1 27. (New) The process of claim 25 wherein the disintegrant is selected from the group  
2 consisting of croscarmellose sodium, polyvinylpyrrolidone and sodium starch  
3 glycolate.

- 4        28.    Cancelled.
- 1        29.    Cancelled.
- 1        30.    Cancelled.
- 1        31.    (Original) The process of claim 20 wherein said granules are dried to an equilibrium  
2        relative humidity of less than at 40% at a bed temperature of not more than 60°C.
- 1        32.    (Currently Amended) The process of claim ~~20~~28 wherein said granules are dried to an  
2        equilibrium relative humidity of less than 25% at a bed temperature of not more than  
3        50°C.
- 1        33.    (Original) The process of claim 20 wherein said dispersible tablet has a disintegration  
2        time of less than one minute.
- 1        34.    (Currently Amended) The process of claim 20 wherein the comprising beta lactamase  
2        inhibitor is as clavulanic acid or a salt thereof, and the beta lactam antibiotic is as  
3        amoxicillin.
- 1        35.    (Currently Amended) The process of claim ~~33~~31 wherein the clavulanic acid salt is  
2        potassium clavulanate.
- 1        36.    (Currently Amended) The process of claim ~~33 or 34~~32 wherein the ratio of  
2        amoxicillin to potassium clavulanate is 12:1 to 1:1.
- 1        37.    (Currently Amended) The process of claim ~~35~~33 wherein the ratio of amoxicillin to  
2        potassium clavulanate is 7:1.
- 1        38.    (Original) The process of claim 20 wherein the tablet when dispersed in an aqueous  
2        media, has a particle size distribution of d90 less than 600 µm.
- 1        39.    (Original) The process of claim 20 wherein the tablet when dispersed in an aqueous  
2        media, has a particle size distribution of d90 less than 400 µm.

- 1       40.   (Original) The process of claim 20 wherein the tablet when dispersed in an aqueous  
2           media, has a particle size distribution of d50 less than 300  $\mu\text{m}$ .
- 1       41.   (Currently Amended) A process for the preparation of a water-dispersible tablet  
2           formulation, the process comprising:
- 3                   aqueous granulation of a  $\beta$ -lactam antibiotic and an intragranular disintegrant,  
4                   incorporated either in the dry mix or in the granulating fluid;
- 5                   drying the granulated mixture;
- 6                   mixing the dried granules with optional extragranular disintegrants, fillers,  
7                   flavours, sweeteners, or lubricating agents; and ~~comprising~~ compressing the  
8                   resulting blend to form water-dispersible tablets.
- 1       42.   (Currently Amended) The process of claim ~~40~~38, wherein the  $\beta$ -lactam antibiotic is  
2           selected from penicillins; cephalosporins; and carbapenems.
- 1       43.   (Currently Amended) The process of claim ~~40~~38, wherein the  $\beta$ -lactam antibiotic is  
2           amoxicillin.
- 1       44.   (Currently Amended) The process of claim ~~40~~38, wherein the disintegrant is selected  
2           from croscarmellose sodium, polyvinylpyrrolidone, and sodium starch glycolate.
- 1       45.   (Currently Amended) The process of claim ~~43~~41, wherein the intragranular  
2           disintegrant is croscarmellose sodium.
- 1       46.   (Currently Amended) The process of claim ~~43~~41, wherein the disintegrant is present  
2           intragranularly at a concentration of about 1 % to about 2.5 % w/w of the tablet  
3           formulation.
- 1       47.   Cancelled.
- 1       48.   Cancelled.

- 1 49. Cancelled.
- 1 50. Cancelled.
- 1 51. Cancelled.
- 1 52. Cancelled.
- 1 53. (Currently Amended) The process of claim 4038, wherein the suspension formed  
2 upon dispersion can completely pass through a 750  $\mu\text{m}$  sieve.
- 1 54. A process for the preparation of a stable amoxicillin dispersible tablet formulation,  
2 ~~wherein amoxicillin and intragranular disintegrant, incorporated either in the dry mix~~  
3 ~~or in the granulating fluid the process comprising: granulation of amoxicillin and~~  
4 intragranular disintegrant; drying the granulated mixture; mixing the dried granules  
5 with optional extragranular disintegrants, fillers, flavours, sweeteners, or lubricating  
6 agents; and ~~comprising~~compressing the resulting blend to form water-dispersible  
7 tablets, wherein amoxicillin and intragranular disintegrant are incorporated either in  
8 the dry mix or in the granulating fluid.
- 1 55. (Currently Amended) The process of claim 5345, wherein amoxicillin comprises  
2 about 30 to about 50 % w/w of the formulation.
- 1 56. (Currently Amended) The process of claim 5345, wherein amoxicillin has a particle  
2 size of  $d_{90}$  less than about 150  $\mu\text{m}$ .
- 1 57. (Currently Amended) The process of claim 5345, wherein amoxicillin has a particle  
2 size of  $d_{90}$  less than about 75  $\mu\text{m}$ .
- 1 58. Cancelled.
- 1 59. Cancelled.
- 1 60. Cancelled.

- 1        61.    Cancelled.
- 1        62.    Cancelled.
- 1        63.    Cancelled.
- 1        64.    Cancelled.
- 1        65.    Cancelled.
- 1        66.    (Currently Amended) The process of claim ~~53~~45, wherein the granules are dried to an  
2            equilibrium relative humidity of less than about 40% at a bed temperature of not more  
3            than about 60°C.
- 1        67.    (Currently Amended) The process of claim ~~65~~45, wherein the granules are preferably  
2            dried to an equilibrium relative humidity of less than about 25% at a bed temperature  
3            of not more than about 50°C.
- 1        68.    Cancelled.
- 1        69.    Cancelled.
- 1        70.    Cancelled.
- 1        71.    Cancelled.
- 1        72.    Cancelled.
- 1        73.    Cancelled.
- 1        74.    (Currently Amended) ~~The A-process of claim 45 for the preparation of a water-~~  
2            ~~dispersible tablet formulation~~ wherein the tablet when dispersed in an aqueous media,  
3            has a particle size distribution of d90 less than 600 µm.

